INDIANA DONOR NETWORK
Saving lives through organ and tissue donation

September 27, 2016

UNOS Member Quality
[redacted]

RE: Indiana Donor Network on-site review

Dear [redacted]:

I am writing in regards to the on-site review at Indiana Donor Network on August 30-31, 2016, which was conducted by UNOS' Member Quality. We have reviewed and completed a full analysis of violations of OPTN Policies 1.2, 2.2, 2.5, 2.6, 2.15.C (previously OPTN Policy 2.15.B), 16.5 (previously OPTN Policy 16.6), and 18.1. We also reviewed the accuracy of information submitted on the Deceased Donor Registration (DDR) forms. The enclosed UNOS Report Responses and Corrective Action Plans provide explanations of the nonconformances identified and the corrective actions to be taken by Indiana Donor Network.

In addition to the Corrective Action Plans provided, Indiana Donor Network will be reviewing our entire QAPI program with the assistance of consultants to ensure a full program is in place to identify, correct, and track nonconformances as well as to derive data that will be utilized to monitor and improve our performance. As part of our corrective action process, the Indiana Donor Network reached out to its peers at the Nevada Donor Network, Gift of Life Michigan and the New Jersey Sharing Network to review how each of these OPOs ensure appropriate brain death declaration and documentation.

At Indiana Donor Network we feel passionately about performance and continually strive to meet all regulatory requirements. We have put significant energy into examining not only the human factors in the errors identified, but also the integrity of procedures employed throughout the organization. We understand that we have some systemic issues and we also understand the severity of all violations identified, including brain death pronouncement documentation which has been escalated to Membership and Professional Standards Committee (MPSC) and Human Resources and Services Administration (HRSA).

We appreciate the UNOS Member Quality's review, which ensures Indiana Donor Network's full compliance with OPTN policies and upholds the integrity of organ donation and transplantation. If you have any questions or need any additional information, please contact me at [redacted]

Sincerely,

[redacted]
President/CEO

[redacted]

Indiana Donor Network **Corrective Action Plan** **Provided to OPTN/UNOS for the** **UNOS Site Survey August 30-31, 2016**	
Section I - Donor Record Review	**A. Critical Data Review**
Area of Non-Compliance #1	The following donor records did not have documentation verifying that death is pronounced according to applicable laws as required by OPTN Policy 2.2 #5: • [redacted]1 – Death pronouncement by physician not included in the donor record. (Pronouncement made by Nurse Practitioner without physician signature.) Documentation of clinical exam consistent with brain death not included in the donor record. Upon request, clinical exam provided by OPO reports patient with "minimal gag reflex" intact. • [redacted] – Documentation of a clinical exam consistent with brain death not included in the donor record and could not be produced by OPO upon request.
Requested Action(s)	Please provide a corrective action plan to ensure accurate data entry and compliance with OPTN Policy 2.2, pronouncement of death and accuracy of serology results recorded in donor file.
Explanations	Indiana law does not exist as to how brain death declaration must occur nor is Indiana Donor Network aware of any federal laws or statutes that exist in regards to how brain death declaration is to be performed in Indiana. While there are guidelines for determining brain death in Indiana, these are only guidelines and not law. Since its inception, the Indiana Donor Network has relied on the hospital expertise only to pronounce brain death. Indiana Donor Network Policy FS B3.000 Verification and Documentation of Brain Death and practice has been to ensure a copy of the hospital brain death documentation is obtained and placed in the donor chart. This documentation per policy has been to ensure it includes that the patient is brain dead, the date/time and a signature by a physician. Staff were inconsistently verifying this documentation. Indiana Donor Network did not have a process for ensuring the integrity of the brain death process.

	Root cause: Inconsistent verification of documentation and no federal law or state statute defining proper documentation of brain death. Lack of internal process for verifying hospital policy is followed or for ensuring integrity of brain death process.
Corrective Action Plan and Estimated Completion Dates	A containment plan was put into place on August 31, 2016. All Quality, Organ Services, Family Services, and Professional Services staff could not sign into our electronic medical records system until they acknowledged receipt of information regarding the containment plan. The acknowledgement notice stated the following: "1) Moving forward, the Family Services Coordinators (FSCs) will be required to ensure that a negative clinical exam and apnea test are documented in the hospital chart and that a copy is made and placed in the Indiana Donor Network chart along with the documentation of brain death pronouncement by a physician. 2) If an NP is documenting the brain death examination, the note must be co-signed by the attending physician that they are working under the direction of. If not co-signed, it cannot be accepted and Indiana Donor Network will not proceed with organ recovery until accurate documentation is received from the hospital. This aligns with hospital contract language stating that 'the determination of death for a Potential Donor shall be made by the Donor's attending physician or by the physician responsible for certifying death at the Hospital.' 3) The FSCs and Organ Recovery Coordinators (ORCs) will add to their hand off/report (documented on the Clinical Pathway) that they have reviewed the documentation of the clinical exam, apnea test, and ancillary procedures (if applicable) and that a copy of these items and the death note have been placed in the Indiana Donor Network chart. 4) The Clinical Quality Assurance Coordinators will be trained that when reviewing donor charts, documentation of a negative clinical exam and apnea test must be present in the Indiana Donor Network chart along with a proper brain death note. Ancillary testing might also be present if performed. Acknowledgement of this notice confirms your understanding of these requirements and indicates your ability to comply with these requirements as stated above. All questions and concerns should immediately be directed to your manager." Please see attached summary of users along with their role and date/time of acknowledgement. This was implemented on August 31, 2016.

	The above was a containment plan implemented immediately while Member Quality was onsite on August 31, 2016. Since then, the following corrective actions will supersede this immediate containment plan. 1. An emergency meeting of the Indiana Donor Network Advisory Board will be held by October 5, 2016 where the Advisory Board will determine minimum standards as to what must be documented in the hospital's brain death note in order for Indiana Donor Network to accept it as a suitable brain death declaration note. This will include that all brain death declarations must be completed by a MD or DO. The Indiana Donor Network Chief Medical Officer will also be part of this meeting in determining standards. 2. Policy FS B3.000 Verification and Documentation of Brain Death will be updated by October 9, 2016 to reflect that the Indiana Donor Network will follow each individual hospital policy for brain death and that at a minimum the recommendations from the Advisory Board as to brain death documentation must occur. Additional updates to this policy will include: o all brain death documentation is uploaded into the appropriate donor case in the "BD Documentation" section of the electronic medical record system. o the organ recovery coordinator/family services coordinator must call the administrator on call (AOC) and have the AOC verify that the brain death note documentation matches the hospital policy and at a minimum has the requirements that the Advisory Board recommended. o the brain death documentation to be verified by the AOC should be reviewed from the attachments section in the electronic medical records system. This review by the AOC will be documented as a case note in the electronic medical record system. 3. An emergency meeting of the Indiana Donor Network Governing Board Executive Committee will be held by October 10, 2016 to approve the recommendations to Policy FS B3.000 Verification and Documentation of Brain Death that was recommended by the Advisory Board. Additionally, the policy will be shared at the next board meeting with all governing board members. 4. Once the policy has been reviewed and approved by the Executive Committee, the Organ Services, Professional Services and Family Services staff will be trained on the policy by October 13, 2016.

5. Indiana Donor Network work instruction WI-ORG-068 Organ Chart QA Process will be created to reflect the key elements that need to be verified as it relates to documentation regarding pronouncement of brain death per FS Policy B3.000 Verification and Documentation of Brain Death. This will be implemented and Organ Services, Quality Assurance Coordinators and Family Services Coordinators will be trained no later than October 13, 2016 on WI-ORG-068 Organ Chart QA Process.
6. The Indiana Donor Network Professional Services staff will do a 100% review of all organ potential hospital brain death policies by September 28, 2016. Each of the hospital policies on brain death will be uploaded into the iTransplant medical charting system for access by the organ recovery coordinators, family services coordinators, professional services coordinators, quality assurance coordinators and any other applicable staff.
7. In the event that an organ hospital does not have a policy on brain death, the professional services staff or a member of leadership will make contact with the hospital to ensure a brain death policy is created and implemented. This contact will be completed by October 5, 2016 and it will be stressed that a policy needs implemented in the next 60 days.
8. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.
9. Professional Services staff, President/CEO and Chief Medical Officer will provide communication to all organ hospitals regarding the necessity to pronounce brain death according to hospital policy but also in regards to the minimum requirements for pronouncing brain death that the Indiana Donor Network Advisory Board recommends and the Executive Committee approves. This will be completed by October 13, 2016.
10. Indiana Donor Network form ORG-002 Clinical Pathway will be updated to ensure brain death is documented properly and reviewed by the AOC. The Clinical Pathway will be updated by October 13, 2016, and family services, organ services and quality assurance coordinators will be trained by October 13, 2016.
11. The Organ Services' new coordinator orientation, Family Services' new coordinator orientation, and new Clinical Quality Assurance Coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.

<table>
<tr><td></td><td>Effectiveness assessment:
Within the electronic medical record system, there is documentation completed on every case that lists the methods used to pronounce brain death. A report will be built to monitor those fields and ensure that the proper methods are being utilized to pronounce brain death. The report will be run daily and emailed to the Managers of Family Services and Organ Services so that they can ensure the information is correct and present in the chart. If documentation is not present they will follow up with the appropriate staff immediately. This will be implemented by October 13, 2016.

The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee, will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.</td></tr>
<tr><td>Area of Non-Compliance #2</td><td>2 of 20 records unverified for serology results

<table><tr><th>Donor ID</th><th>Tiedi documentation</th><th>Donor record documentation</th></tr><tr><td>[redacted]</td><td>HTLV = Not Done</td><td>HTLV = Negative</td></tr></table></td></tr>
</table>

	[redacted]	EBV IgG = Negative EBV IgM = Positive	EBV IgG = Positive EBV IgM = Negative	
Requested Action(s)	Please provide a corrective action plan to ensure accurate data entry and compliance with OPTN Policy 2.2, pronouncement of death and accuracy of serology results recorded in donor file.			
Explanation	[redacted] HTLV is a serology that is not routinely run by our organization on organ donor cases, but is completed on select tissue donor cases at the request of certain tissue processors. The test is ordered/added to the testing panel by the tissue Team Leaders after tissue has been recovered. The results can take up to 5-7 days to receive. Previously, the addition of the HTLV test was not communicated between tissue and the organ Clinical QA Coordinators (the organ chart is looked at separately from the tissue chart and by different coordinators); therefore, the coordinator completing the DDR may not have been aware of an HTLV result needing to be corrected within the DDR. [redacted] **55**- The coordinator transposed the results when they were entered into Tiedi. When this occurred we were utilizing the True North/LifeLogics electronic medical record system. The results had to be manually entered into Tiedi. We now utilize the Transplant Connect/iTransplant electronic medical record system and the DDR is completed through an import of information pulled from iTransplant into Tiedi. Lack of process for verifying documentation. Root cause: Lack of a verification process resulting in a lack of communication.			
Corrective Action Plan and Estimated Completion Dates	1. Serology results were corrected in Tiedi on September 15, 2016. 2. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016.			

	3. On shared organ and tissue cases, a QA team member will share HTLV results with the organ transplant programs. This is current practice and will remain part of the continuing process. 4. These changes will be reflected in Indiana Donor Network work instruction WI-QS-009 Completing the Deceased Donor Registration. This will be implemented no later than October 5, 2016. 5. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. 6. A report will be created enabling Quality Assurance staff to monitor the tests that are pending for both organ and tissue cases so that they can follow up on obtaining results. This will be implemented no later than October 13, 2016. 7. Indiana Donor Network Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to require a review of serologies entered into the EMR by the AOC. These forms will be updated by October 5, 2016, and family services, organ services and quality assurance coordinators will be trained by October 5, 2016. Effectiveness Assessment: Compliance will be measured through our internal audit process. Internal audit 004 "Organ Donor Suitability & Positive Serologies" will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart on cases where organ and tissue was recovered. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRA documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion

	and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	B. OPTN Policy Review
Area of Non-Compliance #3	The following donor record did not have documentation of a confirmatory test for brain death in the donor record as required by OPTN Policy 2.2 (pronouncement of death). • [redacted] (Apnea test was aborted due to donor instability)
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	Indiana law does not exist as to how brain death declaration must occur nor is Indiana Donor Network aware of any federal laws or statutes that exist in regards to how brain death declaration is to be performed in Indiana. While there are guidelines for determining brain death in Indiana, these are only guidelines and not law. Since its inception, the Indiana Donor Network has relied on the hospital expertise only, to pronounce brain death. Indiana Donor Network policy and practice has been to ensure a copy of the hospital brain death documentation is obtained and placed in the donor chart. This documentation per policy has been to ensure it includes that the patient is brain dead, the date/time and a signature by a physician. Staff were inconsistently verifying this documentation. Indiana Donor Network did not have a process for ensuring the integrity of the brain death process. <u>Root cause:</u> Inconsistent verification of documentation and no federal law or state statute defining proper documentation of brain death. Lack of internal process for verifying hospital policy is followed or for ensuring integrity of brain death process.

Corrective Action Plan and Estimated Completion Dates	A containment plan was put into place on August 31, 2016. All Quality, Organ Services, Family Services, and Professional Services staff could not sign into our electronic medical records system until they acknowledged receipt of information regarding the containment plan. The acknowledgement notice stated the following: "1) Moving forward, the Family Services Coordinators (FSCs) will be required to ensure that a negative clinical exam and apnea test are documented in the hospital chart and that a copy is made and placed in the Indiana Donor Network chart along with the documentation of brain death pronouncement by a physician. 2) If an NP is documenting the brain death examination, the note must be co-signed by the attending physician that they are working under the direction of. If not co-signed, it cannot be accepted and Indiana Donor Network will not proceed with organ recovery until accurate documentation is received from the hospital. This aligns with hospital contract language stating that 'the determination of death for a Potential Donor shall be made by the Donor's attending physician or by the physician responsible for certifying death at the Hospital.' 3) The FSCs and Organ Recovery Coordinators (ORCs) will add to their hand off/report (documented on the Clinical Pathway) that they have reviewed the documentation of the clinical exam, apnea test, and ancillary procedures (if applicable) and that a copy of these items and the death note have been placed in the Indiana Donor Network chart. 4) The Clinical Quality Assurance Coordinators will be trained that when reviewing donor charts, documentation of a negative clinical exam and apnea test must be present in the Indiana Donor Network chart along with a proper brain death note. Ancillary testing might also be present if performed. Acknowledgement of this notice confirms your understanding of these requirements and indicates your ability to comply with these requirements as stated above. All questions and concerns should immediately be directed to your manager." Please see attached summary of users along with their role and date/time of acknowledgement. The implementation date was August 31, 2016. The above was a containment plan implemented immediately while Member Quality was onsite on August 31, 2016. Since then, the following corrective actions will supersede this immediate containment plan.

	1. An emergency meeting of the Indiana Donor Network Advisory Board will be held by October 5, 2016 where the Advisory Board will determine minimum standards as to what must be documented in the hospital's brain death note in order for Indiana Donor Network to accept it as a suitable brain death declaration note. This will include that all brain death declarations must be completed by a MD or DO. The Indiana Donor Network Chief Medical Officer will also be part of this meeting in determining standards. 2. Policy FS B3.000 Verification and Documentation of Brain Death will be updated by October 9, 2016 to reflect that the Indiana Donor Network will follow each individual hospital policy for brain death and that at a minimum the recommendations from the Advisory Board as to brain death documentation must occur. Additional updates to this policy will include: o all brain death documentation is uploaded into the appropriate donor case in the "BD Documentation" section of the electronic medical record system. o the organ recovery coordinator/family services coordinator must call the administrator on call (AOC) and have the AOC verify that the brain death note documentation matches the hospital policy and at a minimum has the requirements that the Advisory Board recommended. o the brain death documentation to be verified by the AOC should be reviewed from the attachments section in the electronic medical records system. This review by the AOC will be documented as a case note in the electronic medical record system. 3. An emergency meeting of the Indiana Donor Network Governing Board Executive Committee will be held by October 10, 2016 to approve the recommendations to Policy FS B3.000 Verification and Documentation of Brain Death that was recommended by the Advisory Board. Additionally, the policy will be shared at the next board meeting with all governing board members. 4. Once the policy has been reviewed and approved by the Executive Committee, the Organ Services, Professional Services and Family Services staff will be trained on the policy by October 13, 2016. 5. Indiana Donor Network work instruction WI-ORG-068 Organ Chart QA Process will be created to reflect the key elements that need to be verified as it relates to documentation regarding pronouncement of brain death per FS Policy B3.000 Verification and Documentation of Brain Death. This will be implemented and Organ

	Services, Quality Assurance Coordinators and Family Services Coordinators will be trained no later than October 13, 2016 on WI-ORG-068 Organ Chart QA Process. 6. The Indiana Donor Network Professional Services staff will do a 100% review of all organ potential hospital brain death policies by September 28, 2016. Each of the hospital policies on brain death will be uploaded into the iTransplant medical charting system for access by the organ recovery coordinators, family services coordinators, professional services coordinators, quality assurance coordinators and any other applicable staff. 7. In the event that an organ hospital does not have a policy on brain death, the professional services staff or a member of leadership will make contact with the hospital to ensure a brain death policy is created and implemented. This contact will be completed by October 5, 2016 and it will be stressed that a policy needs implemented in the next 60 days. 8. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016. 9. Professional Services staff, President/CEO and Chief Medical Officer will provide communication to all organ hospitals regarding the necessity to pronounce brain death according to hospital policy but also in regards to the minimum requirements for pronouncing brain death that the Indiana Donor Network Advisory Board recommends and the Executive Committee approves. This will be completed by October 13, 2016. 10. Indiana Donor Network form ORG-002 Clinical Pathway will be updated to ensure brain death is documented properly and reviewed by the AOC. The Clinical Pathway will be updated by October 13, 2016, and family services, organ services and quality assurance coordinators will be trained by October 13, 2016. 11. The Organ Services' new coordinator orientation, Family Services' new coordinator orientation, and new Clinical Quality Assurance Coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016. <u>Effectiveness assessment:</u> Within the electronic medical records system, there is documentation completed on every case that lists the methods used to pronounce brain death. A report will be built to monitor those fields and ensure that the proper methods are being utilized to pronounce brain death. The report will be run daily and emailed to the Managers of Family Services and Organ

	Services so that they can ensure the information is correct and present in the chart. If documentation is not present they will follow up with the appropriate staff immediately. This will be implemented by October 13, 2016. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #4	The following donor records did not have donor record documentation of an archived sample as required by OPTN Policy 2.2: • [redacted]6 (lab contacted for documentation) • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	This occurred because we did not have any checks within the QA process to ensure that the statement was on the final HLA report received from the lab who archives the serum for us.

	They did produce updated documentation during the audit verifying that there was archived serum available for these two donors. Root cause: Lack of QA process
Corrective Action Plan and Estimated Completion Dates	1. All donor records from August 1, 2015 through current have been checked to ensure that the statement regarding an archive sample is present on the final report received from the lab archiving serum for organ donors. 2. Indiana Donor Network work instruction WI-ORG-068 will be created to reflect that all final HLA reports must have the statement "1.5 mL of serum is archived on this donor and will be saved for a minimum of 10 years." If the statement is not present, the lab will be contacted by the Clinical QA Coordinator to find out if there is archive serum at the lab. If there is, an amended report will be requested. If there is no serum archive, a reportable event will be written and the investigation will be completed and documented through the CAPA process. This will be implemented no later than October 5, 2016. 3. The Clinical QA Coordinators will be trained on WI-ORG-068 by October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 015 "Organ Donor Records" will have an audit item added where the auditor will perform a random chart sampling to verify that the statement "1.5 mL of serum is archived on this donor and will be saved for a minimum of 10 years" appears on all final HLA reports sampled. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in

	this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #5	The following donor records did not have a properly documented hemodilution calculation for serological testing as required by OPTN Policy 2.5: • [redacted] • [redacted] • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	Internal policies and work instructions were not specific enough with regards to how the hemodilution needs to be completed. Specific information was outlined regarding blood products and colloids, but little guidance was given in regards to documenting crystalloids; therefore, documentation was inconsistent from one coordinator to another. Proper education for the Organ Recovery Coordinators related to the hemodilution calculation, specifically when crystalloids were a factor, was lacking. <u>Root cause:</u> Lack of training and competency.
Corrective Action Plan and Estimated Completion Dates	1. Indiana Donor Network forms ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the blood bank needs to be contacted prior to completing the hemodilution on all cases to confirm the amount of blood products released/administered to the patient. If available, the blood administration records

	must be copied and placed in the donor record. If not available, it must be documented why they could not be obtained. This will also be updated in policy ORG A8.000 Serology Hemodilution Qualification. These updates will be made no later than October 5, 2016. 2. All Organ Services staff and Clinical Quality Assurance Coordinators will be trained on the policy and form updates prior to implementation and no later than October 5, 2016. 3. The Organ Services and Quality Assurance staff will be retrained on the hemodilution calculation. This education will include the rationale for performing the hemodilution, the components of the hemodilution (blood products, colloids, and crystalloids) and how they affect the sample, how to properly document the hemodilution, and what to do if the sample is found to be hemodiluted. There will also be a test to assess knowledge and understanding of the material presented. All staff will need to pass the test/assessment with 100%. This will be complete by all staff affected no later than October 5, 2016. 4. The Organ Services and Quality Assurance staff will be tested on hemodilution concepts, at a minimum, annually, once being released from orientation. The orientation training over hemodilution will also be assessed and updated to include what is outlined above and will be implemented no later than October 5, 2016. Effectiveness assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends

	are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #6	The following donor record did not have documentation of urinalysis within 24 hours of cross clamp as required by OPTN Policy 2.8: • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	A urinalysis was conducted within 24 hours of cross clamp, but the results were not documented in the electronic medical record and were thus not available at the time of inspection to the inspectors. Root cause: Lack of verification process for ensuring that tests that were performed without results being received prior to the OR were obtained after procurement.
Corrective Action Plan and Estimated Completion Dates	1. The urinalysis results were obtained from the donor hospital and documented in the donor record (please see attached copy). 2. A checklist (has been assigned ORG-098 Case Hand Off Report as an identifier) will be made for Organ Recovery Coordinators to complete at the end of a case in order to communicate to the QA staff any testing that needs followed up on post case (i.e. pending tests, pending biopsy reports, etc.). The checklist will be implemented no later than October 5, 2016. 3. The checklist will be added to Indiana Donor Network policy ORG C1.000 Local Donor Chart Documentation and Completion. The policy will be updated and effective no later than October 5, 2016. 4. Indiana Donor Network form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that prior to entering the OR, the ORC must verify that a urinalysis with micro was performed within 24 hours of when cross clamp is expected to occur. If one has not been performed that will meet this timeframe, a

	urinalysis with micro will be ordered. These forms will be updated and effective no later than October 5, 2016. 5. Indiana Donor Network Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm urinalysis results of no more than 24 hours prior to entering OR are in the EMR. These forms will be updated and effective no later than October 5, 2016. 6. An automated report will be created and sent to QA weekly that lists the donors from the week, cross clamp date and time, and date and time of the latest U/A documented in the OPO EMR. This will be reviewed by the Manager, Business Analytics and Regulatory Compliance with the QA team to ensure compliance. This will be implemented no later than October 13, 2016. 7. All Organ Services and Quality Assurance Coordinators will be trained on the new form, the updated clinical pathways, and policy updates no later than October 5, 2016. Effectiveness assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

	The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #7	The following donor records did not have documentation of flush solution and/or additive lot numbers as required by OPTN Policy 2.15.C (previously OPTN Policy 2.15.B): • [redacted] (Prostin) • [redacted] (Viaspan, Perfadex, Plasmalyte) • [redacted]6 (Viaspan)
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	The solutions and/or additives were for products brought into the OR by either out-of-state centers or the local thoracic teams. The Indiana Donor Network Organ Recovery Coordinators failed to remember to obtain the necessary information and when the transplant centers were contacted they did not have record of the information needed. For abdominal recoveries performed by our local transplant centers, this information is captured in our inventory system. For all other recoveries we rely on the Organ Recovery Coordinators to remember to obtain the information from the other transplant centers involved, but there is no visual reminder currently. <u>Root cause:</u> Lack of appropriate forms, processes, and accountability measures.
Corrective Action Plan and Estimated Completion Dates	1. The Verification of Donor Information form (ORG-063) will be updated to include fields to document the solutions, additives, lot number and expiration dates of the items used in the recovery of the organs. This will be implemented no later than October 5, 2016. 2. Indiana Donor Network Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm fields to document the solutions, additives, lot number and expiration dates of the items used in the recovery of organs have been completed on ORG-063. These forms will be updated and effective no later than October 5, 2016. 3. Policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs will be updated to reflect where the lot and expiration information will be captured for all solutions and additives used in the OR by out-of-state centers and local thoracic transplant centers. This will be implemented no later than October 5, 2016.

	4. All ORC staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates as well as the importance of documenting this information no later than October 5, 2016. Effectiveness assessment: Internal audit 007 Organ Donor Management, Allocation, and Recovery contains an item where the lot/expiration information needs to be verified in a random sampling of charts. This item will be updated to include that the random sampling of charts must include cases where either out-of-state recovery teams or local thoracic teams were involved in the recovery of organs will be checked to verify that all lot and expiration information is present for the solutions/additives used in the OR. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

	The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #8	The following donor records contained a generic statement signed by two individuals stating that all organs and vessels were packaged and verified in accordance with OPTN Policy 5.0. This generic statement did not cite current policy at time of procurement as required by OPTN Policy 16.5 (previously OPTN Policy 16.6): • [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • ACL3151
Requested Action(s)	Please [redacted] a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	Form ORG-063 Verification of Donor Information and Packaging/Labeling was updated to reflect the change from OPTN Policy 5.0 to OPTN Policy 16 on July 1, 2015. For the cases listed, OPO staff utilized a version of the form that was printed from the OPO EMR which did not include the updated language. There was not clear communication that the OPO form ORG-063 should be used in order to ensure compliance. Root cause: Lack of communication between quality and organ staff as to proper form to use.
Corrective Action Plan and Estimated Completion Dates	1. The best practices "Verification for Accuracy of Documentation and Packaging of Transplantable Organs" form provided by the UNOS audit staff will be implemented (has been assigned ORG-097 as an identifier). It will be referenced in policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs and ORG A13.000 Packaging and Labeling of Organs. This form and policy updates will be implemented no later than October 5, 2016.

	2. All Organ Services staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates prior to implementation and no later than October 5, 2016. Effectiveness assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #9	The following donor record did not have documentation of two individuals verifying organ and vessel packaging and labeling at the same time as required by OPTN Policy 16.5 (previously OPTN policy 16.6). Cross clamp was 4/20/2016 – 0309. First verifier signed the generic form on 4/20/16 – 0405. Second verifier signed the form on 4/22/16 – 1313. • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).

Explanation	The second verifier failed to sign the form when the verification took place and instead signed the form two days later when it was caught by another coordinator during review. Root cause: ORC did not follow policy.
Corrective Action Plan and Estimated Completion Dates	1. The best practices "Verification for Accuracy of Documentation and Packaging of Transplantable Organs" (has been assigned ORG-097 as an identifier) form provided by the UNOS audit staff will be implemented. It will be referenced in policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs and ORG A13.000 Packaging and Labeling of Organs. This form and policy updates will be implemented no later than October 5, 2016. 2. Indiana Donor Network Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm two individuals have verified organ and vessel packaging and labeling at the same time. These forms will be updated and effective no later than October 5, 2016. 3. All Organ Services staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates prior to implementation and no later than October 5, 2016. 4. Previously, reportable events were not consistently initiated when signatures were missing from ORG-063, but instead correction requests were initiated. WI-ORG-068 will be created and reflect that if the verification does not take place at the same date/time for both coordinators involved, or if there is a missing signature, date, or time on the "Verification for Accuracy of Documentation and Packaging of Transplantable Organs" (has been assigned ORG-097 as an identifier) form a reportable event must be initiated and a case note must be written by the ORC as to why the procedure was not followed. This will be implemented no later than October 5, 2016 and all Organ Services and Quality Assurance staff will be trained on these changes prior to the implementation date. Effectiveness assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of

<table>
<tr><td></td><td>the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.</td></tr>
<tr><td></td><td>C. Data Validation</td></tr>
<tr><td>Area of Non-Compliance #10</td><td>Validation of data submitted in Tiedi for Deceased Donor Registration (DDR) forms.

5 DDR forms reviewed
4 DDR forms with errors
13 total number of errors

<table>
<tr><th>Donor ID</th><th>Tiedi documentation</th><th>Donor record documentation</th></tr>
<tr><td>[redacted]</td><td>Organ Recovery:
Chest X-ray = Abnormal - left</td><td>Organ Recovery:
Chest X-ray = Abnormal - both</td></tr>
<tr><td>[redacted]</td><td>Organ Recovery:</td><td>Organ Recovery:</td></tr>
</table></td></tr>
</table>

		Date and Time agonal phase begins (systolic BP < 80 or O2 sat. < 80%): 04/17/2016 - 12:12 The OPO did not provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death.	Date and Time agonal phase begins (systolic BP < 80 or O2 sat. < 80%): 04/17/2016 - 12:16 The OPO had data available through 12:22 in the donor record. Time of death is 04/17/2016 - 12:25	
	[redacted]	**Procurement and Authorization:** Date and time authorization obtained for organ donation: 04/08/2016 - 14:39 **Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Other/Specify: No medications listed.	**Procurement and Authorization:** Date and time authorization obtained for organ donation: Unable to verify. (time) **Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Other/Specify: Keppra	

		Organ Recovery: The OPO did not provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death. Liver Biopsy: No	**Organ Recovery:** The OPO had data available through 01:04 in the donor record. Time of death is 04/20/2016 - 01:08. Liver Biopsy: Yes, received biopsy report from the transplant center on 05/03/2016.	
	[redacted]	**Clinical Information:** Serology: HTLV Serology Results: Not Done West Nile Serology Results: Negative West Nile NAT Results: Not Done	**Clinical Information:** Serology: HTLV Serology Results: Negative West Nile Serology Results: Not Done West Nile NAT Results: Negative	

		Donor Management: (Any medications administered within 24 hours prior to cross clamp.) Diuretics: No Arginine Vasopressin: No Inotropic Medications at Time of Cross Clamp: No	**Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Diuretics: Yes, Mannitol given in the OR Arginine Vasopressin: Yes Inotropic Medications at Time of Cross Clamp: Yes, Levophed running at cross clamp per anesthesia record.	
Requested Action(s)	Please make corrections in Tiedi on these DDRs and submit a corrective action plan to ensure that similar errors do not occur in the future.			
Explanation	[redacted] The final chest x-ray was entered into the OPO electronic medical record after the DDR was validated. The chest x-ray result that was entered was the last result documented at the time of DDR validation. The DDR was not updated when the final chest x-ray was updated in the OPO EMR. [redacted] The DDR in Tiedi will validate without the serial data being entered; therefore, there was no indicator to the person validating the information that the serial data was missing. Many of the data fields within Tiedi are now completed by importing data from our electronic medical record into the DDR, but the serial data is not included in the import and must be hand entered by a coordinator prior to validating the document. [redacted] The date and time authorization was obtained for organ donation: this case was a DCD case. The family completed authorization and a partial DRAI on 4/17/16 at 16:29. After further discussions with the doctor, the family decided to wait an additional 24 hours to withdraw care. The following day, 4/18/16 the family decided to withdraw care and move forward with the donation process. The Family Service Coordinator had the family amend the authorization for when they decided to proceed with the donation process on 4/18/16. When			

	the authorization was Reviewed, this was brought to the attention of the Manager, Business Analytics & Regulatory Compliance and the Manager, Family Services. The Family Service Coordinator was counseled to change the authorization date/time back to the date/time it was completed (4/17/16 16:29) and was re-trained that the date/time of an authorization should always be documented when it is completed and not changed if there is a delay in the case. In regards to the Keppra not being documented in Tiedi- this was due to a coordinator not following policy on what is documented on the DDR. The DDR in Tiedi will validate without the serial data being entered; therefore, there was no indicator to the person validating the information that the serial data was missing. Many of the data fields within Tiedi are now completed by importing data from our electronic medical record into the DDR, but the serial data is not included in the import and must be hand entered by a coordinator prior to validating the document. In the OPO electronic medical record, the liver data page had biopsy performed marked as no, but at the bottom of the page it was noted that a biopsy would be performed at the accepting transplant center. When the biopsy results were received, they were not entered on the liver data page and should have been, as that information is imported from the EMR into Tiedi. [redacted] Multiple coordinators entered serology results into the serology result page in the OPO EMR and that information is eventually imported over to Tiedi to complete the DDR. The information entered was not Reviewed against the results in the chart and, therefore, errors were made documenting which serology tests were performed. In regards to the data entry errors surrounding medications administered, the QA Coordinator validating the DDR did not check the Intraoperative Management page in the OPO record or the anesthesia flowsheet. <u>Root cause:</u> Lack of alignment of processes for Organ department staff entering and validating DDRs and Quality Services staff performing quality check of donor record. Lack of training and competency.
Corrective Action Plan and Estimated Completion Dates	1. All information identified by site surveyors was corrected in Tiedi September 18, 2016. 2. When the Clinical Quality Coordinator is ready to close a chart, one of the final steps will be to run an audit report to see if any fields that populate into the DDR have changed since the date the DDR was submitted. This will be included on WI-ORG-068 Organ Chart QA Process. These will be implemented no later than October 5, 2016.

	3. All Quality Assurance staff will be trained on the process change and the work instruction no later than October 5, 2016. 4. A report that can pull the serial data from the OPO EMR into the DDR will be implemented no later than October 13, 2016. 5. Indiana Donor Network form ORG-052 DCD Clinical Pathway will be updated to reflect that vital signs must be documented every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death. These updates will be made by October 5, 2016. 6. All Quality Assurance and Organ Recovery staff will be trained on the process change, updated pathway, and updates to the work instruction no later than October 5, 2016. 7. Family Services staff will receive education regarding the completion of the authorization/disclosure paperwork, what to do if a case is delayed for any reason, and the proper way to make error corrections. This will all occur by October 5, 2016. 8. Organ staff will be retrained on marking the liver data page appropriately when a biopsy is performed, even if it is not performed locally, as well as the effects of not marking this information appropriately. This will be completed by October 5, 2016. 9. A checklist (has been assigned ORG-098 Case Hand Off Report as an identifier) will be made for Organ Recovery Coordinators to complete at the end of a case in order to communicate to the QA staff any testing that needs followed up on post case (i.e. pending tests, pending biopsy reports, etc.). The checklist will be implemented no later than October 5, 2016 and staff will be trained on the form. 10. Quality Assurance Coordinators and Organ Recovery Coordinators will be re-trained regarding entry of biopsy results on the anatomy pages in the OPO EMR to ensure correct information is imported into the DDR. Retraining will be completed with appropriate staff no later than October 5, 2016. 11. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 12. These changes will be reflected in Indiana Donor Network work instruction WI-QS-009 Completing the Deceased Donor Registration and WI-ORG-068 Organ Chart QA

	Process. Additionally, the places to look in the donor record for certain information will be added to the WI-QS-009 to ensure that all locations for information have been checked prior to DDR validation. This will be implemented no later than October 5, 2016. 13. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 004 "Organ Donor Suitability & Positive Serologies" will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart on cases where organ and tissue was recovered. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance. The corrective action process will be followed for any non-conformances identified. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.

<table>
<tr><td>Area of Non-Compliance #11</td><td>Validation of data submitted for Donor Summaries

5 donor summaries were reviewed
2 of 5 summaries with errors

<table>
<tr><th>Donor ID</th><th>Tiedi documentation</th><th>Donor record documentation</th></tr>
<tr><td>[redacted]</td><td>Donor Information:
Admit Date: 02/11/2016 - 01:00</td><td>Donor Information:
Admit Date: 02/11/2016 - 02:19</td></tr>
<tr><td>[redacted]</td><td>Medical and Social History:
History of hypertension, compliant with treatment: Yes

Medical and social history comments:
"Patient did have HTN for the past 5 or 6 years and was on medications for control."

Infectious Diseases:
Anti-HTLV I/II: Not Done</td><td>Medical and Social History:
History of hypertension, compliant with treatment: Unable to verify

Medical and social history comments:
Per mother on DRAI, the donor "never took medication for it."

Infectious Diseases:
Anti-HTLV I/II: Negative</td></tr>
</table>
</td></tr>
<tr><td>Requested Action(s)</td><td>Please provide a corrective action plan that shows how the OPO will ensure the accuracy of data entered into DonorNet.</td></tr>
</table>

Explanation	[redacted] The date/time of admission was changed by the tissue team after they verified the information with the hospital face sheet. There is no process for the organ staff to know to change this in UNET. [redacted] **68**- The donor hospital record listed that the patient was compliant with taking medication for their BP which did not align with what the historian provided during the health assessment interview. Root cause: Lack of alignment of processes for Organ department staff entering and validating DonorNet Summaries and Quality Services staff performing quality control of the donor record. No hierarchy of priority of information to be documented.
Corrective Action Plan and Estimated Completion Dates	1. WI-FS-008 Referral process will be updated to reflect that the FSC or ORC who performs the first onsite for the referral will verify the date/time of admission per the hospital face sheet and ensure that the documentation in the OPO EMR is correct. The work instruction will be updated and all FSCs and ORCs trained on the changes no later than October 5, 2016. 2. The Anti-HTLV I/II result was updated to Negative in the DDR on September 18, 2016. We are unable to change the medical-social history comments within UNET. 3. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 4. These changes will be reflected in Indiana Donor Network work instruction WI-QS-009 Completing the Deceased Donor Registration. This will be implemented no later than October 5, 2016. 5. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. 6. A report will be created enabling Quality Assurance staff to monitor the tests that are pending for both organ and tissue cases so that they can obtain tests and ensure compliance. This will be implemented no later than October 13, 2016.

	7. WI-QS-009 Completing the Deceased Donor Registration will be updated to explain ``what should be done if the information in the hospital chart differs from what the historian reports in the UDRAI. The updates will be completed and Quality Assurance Coordinators and Organ Recovery Coordinators will be trained on the updates by October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 004 "Organ Donor Suitability & Positive Serologies" will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	D. Priority UNOS Member Quality Management Review – MPSC Review
Section II – Policy Review and Process Validation	**A. OPTN Policy 2.6 Deceased Donor Blood Type Determination and Reporting**
Area of Non-Compliance #12	The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review: • Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016 As part of the survey process, OPO protocols/polices were reviewed to verify compliance with OPTN Policies. The findings of this review are as follows:

<table>
<tr><td></td><td>
<table>
<tr><th>Required Element</th><th>Element in Protocol</th></tr>
<tr><td>Tests were completed using two separate blood samples</td><td>Verified</td></tr>
<tr><td>Protocol to resolve conflicting primary blood types</td><td>Verified</td></tr>
<tr><td>Verification that two individuals performing blood type reporting each consulted source documents</td><td>Verified</td></tr>
<tr><td>Verification occurs prior to the match run or in cases of accelerated donation, verification occurs prior to organ release to the transplant hospital.</td><td>Unable to verify, accelerated donation element is not present.</td></tr>
</table>
During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about how they perform ABO verification. Site surveyors validated that OPO staff practices align with the OPO's policies and procedures related to OPTN Policy 2.6.
</td></tr>
<tr><td>Requested Action(s)</td><td>Please provide a corrective action plan to ensure compliance with OPTN Policy 2.6.</td></tr>
<tr><td>Explanation</td><td>Language regarding how ABO verification must occur in the case of an accelerated donation was not incorporated when updating policy ORG A17.000 ABO confirmation.

<u>Root Cause:</u>
<u>Lack of a process to ensure all regulation updates are implemented in policy and practice.</u></td></tr>
<tr><td>Corrective Action Plan and Estimated Completion Dates</td><td>1. Policy ORG A17.000 ABO Confirmation will be updated to include language regarding cases of accelerated donation and verification occurring prior to organ release to the transplant hospital. The policy updates will be implemented no later than October 5, 2016.</td></tr>
</table>

	2. All Organ Services staff and Quality Staff will be trained on the policy updates prior to implementation and no later than October 5, 2016. 3. When UNOS, CMS, or other regulatory policy language is updated, the Manager, Business Analytics and Regulatory Compliance is notified of changes via email from all of the regulatory bodies (UNOS, CMS, etc.). The Manager, Business Analytics and Regulatory Compliance or designee will notify appropriate department leaders that policy updates affecting their respective department(s) may be necessary. The appropriate department leader(s) will be responsible for updating all affected policies, forms, and/or work instructions in Indiana Donor Network's document management system by the deadline provided by the Manager, Business Analytics and Regulatory Compliance or designee as he/she deems appropriate. The Manager, Business Analytics and Regulatory Compliance or designee will review the updated policies, forms, and work instructions to ensure all information is updated according to regulatory policy language and becomes effective as defined by the regulatory body. Corrections or additional updates may be required by department leaders. Department leaders will be responsible for retraining of staff as appropriate. The Quality Systems Coordinator will update the internal audit matrixes within the same time frame that is given to department leadership to make policy updates. The updated audit matrixes will then be reviewed for accuracy by the Manager, Business Analytics and Regulatory Compliance. Additionally, prior to any audit beginning, the Quality Systems Coordinator will ensure a review of the most current UNOS and CMS policies and ensure alignment of the audit with these policies. 4. Policy ORG D2.000 Implementation of new UNOS policies and QS B1.000 Policies and Procedures Document Control will be updated to reflect these changes and implemented no later than October 5, 2016. 5. Organ Services leadership staff, the Manager, Business Analytics & Regulatory Compliance and the Quality Systems Coordinator will all be trained on the policy updates prior to implementation and no later than October 5, 2016. <u>Effectiveness Assessment:</u> The Quality Systems Coordinator will continue to perform annual audits to ensure regulatory policy language is accurately reflected in all applicable internal policies.

	An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	B. OPTN Policy 2.6.B Deceased Donor Blood Subtype Determination
Area of Non-Compliance #13	The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review: • Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016 As part of the survey process, OPO protocols/policies were reviewed to verify compliance with OPTN Policies. The findings of this review are as follows:

Required Element	Element in Protocol
Tests were completed using two separate blood samples	Verified
Samples used were pre red blood cell transfusion	Unable to verify
If conflicting subtype results, the subtype must not be reported	Verified

During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about their knowledge regarding the process for subtyping of blood group A donors. Based on staff interviews, there was a knowledge gap regarding the content of the OPO's Policy 17.000, Revision: 11 and the OPO's staff practices.

During the interviews, it was determined that staff were inconsistent in verbalizing the requirement for pre red blood cell transfusion samples in subtyping, confusing pre-transfusion with hemodilution.

Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policy 2.6.B.
Explanation	A knowledge gap was identified surrounding pre-transfusion versus hemodilution and needs to be corrected with the Organ Services department. Root Cause: Lack of training and competency assessment of pre-transfusion samples and hemodilution.
Corrective Action Plan and Estimated Completion Dates	1. All Organ Services staff will receive retraining regarding subtype determination. Education will include rationale for subtyping, rationale for why a pre red blood cell transfusion sample is needed and how that differs from a pre-transfusion sample for performing a hemodilution, as well as the negative effects that could come about if this policy requirement was not fulfilled. The training and demonstrated competency will be completed no later than October 5, 2016. 2. Indiana Donor Network Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm ABO in the EMR. These forms will be updated and effective no later than October 5, 2016. 3. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016. Effectiveness Assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

<table>
<tr><td></td><td>An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.</td></tr>
<tr><td></td><td>C. OPTN Policies 1.2 Definitions and 2.15.B Pre-recovery Verification – No Requested Action</td></tr>
<tr><td>Section III – Data Submission</td><td>A. Deceased Donor Registrations (DDRs) forms</td></tr>
<tr><td>Area of Non-Compliance #14</td><td>Indiana Donor Network had the following late DDR submissions between July 1, 2014 – July 1, 2016. There were 7 of 338 (2%) late DDR submissions during this time period. See below for details.
<table>
<tr><th>Donor ID</th><th>Last Name</th><th>First Name</th><th>Date Donor Added</th><th>DDR Expected Date</th><th>Date DDR First Validated</th><th>Days Over-due</th></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>15NOV2014</td><td>18DEC2014</td><td>19DEC2014</td><td>1</td></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>11FEB2016</td><td>15MAR2016</td><td>20MAR2016</td><td>5</td></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>11FEB2016</td><td>15MAR2016</td><td>20MAR2016</td><td>5</td></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>12FEB2016</td><td>17MAR2016</td><td>20MAR2016</td><td>3</td></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>13FEB2016</td><td>18MAR2016</td><td>21MAR2016</td><td>3</td></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>01APR2016</td><td>06MAY2016</td><td>07MAY2016</td><td>1</td></tr>
<tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td><td>03APR2016</td><td>06MAY2016</td><td>07MAY2016</td><td>1</td></tr>
</table>
DDR forms must be submitted within 30 days as required by Policy 18.1, Table 18-1 (previously OPTN Policy 7.2).</td></tr>
<tr><td>Requested Action(s)</td><td>Please submit a corrective action plan to ensure that DDR forms will be submitted within the required thirty days as required by Policy 18.1 (previously OPTN Policy 7.2).</td></tr>
<tr><td>Explanation</td><td>During the time period specified, the manner in which DDRs are completed was updated but there was a lot of confusion among coordinators on how to do this and who was responsible for completing the DDR in a timely manner. Who was responsible for the completion of the</td></tr>
</table>

	DDR was not being formally tracked or enforced in any way. Because of volume and process changes, some of the DDRs were completed outside of the 30-day window specified. Root Cause: Lack of alignment of processes for Organ department staff entering and validating DonorNet Summaries and Quality Services staff performing quality control of the donor record.
Corrective Action Plan and Estimated Completion Dates	1. At the conclusion of a case, the Organ Recovery Coordinators are to complete the DDR Entry and Summary page in the electronic medical record system. When the Feedback document is completed in UNET by the Clinical QA Coordinator or Quality Coordinator, they will assign a task in the electronic medical record for the final two Organ Recovery Coordinators on the case to complete any of the DDR Entry and Summary page that has not yet been completed. The ORCs will have 10 calendar days to complete this task. Once the task is marked as complete in the EMR, it will send an email to the quality staff who assigned the task stating that the task has been closed. This will alert the quality staff that the DDR is ready to be Reviewed and validated. 2. Policy ORG-C6.000 Data Submission, WI-QS-009 Completing the Deceased Donor Registration, and WI-QS-010 Completing the Donor Organ Disposition will all be updated to reflect the changes outlined above. These updates will be effective no later than October 5, 2016. 3. All Organ Services staff, Quality Assurance Coordinators and Quality Coordinators will be trained on these changes prior to implementation and no later than October 5, 2016. 4. A report will be created that is sent daily to the Manager, Business Analytics & Regulatory Compliance showing pending Feedback, PTRs, and DDR information. Pending reports that are due within 10 days will be highlighted and the Manager, Business Analytics & Regulatory Compliance will be responsible for ensuring reports are completed on time. This update will be effective no later than October 13, 2016. Effectiveness Assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of

	Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016. Additionally, monthly, Indiana Donor Network will request data submission compliance reports from UNOS and verify compliance of all reports. A corrective action process will be implemented in the event Indiana Donor Network is out of compliance.
	B. Donor organ disposition (feedback) – No Requested Action
	C. Potential Transplant Recipient (PTRs) refusal codes – No Requested Action
Section IV	**A. Monthly Death Notification Information**
Area of Non-Compliance #15	UNOS reviewed the OPO's methodology for reporting death notification information in UNet. Two donor records were reviewed to determine the accuracy of the OPO's use of the definition of an "Eligible Death" as defined in OPTN Policy 1.2. The number of donor records included all brain dead non-eligible donors < 71 years old. The review identified two donors the OPO should have reported as Eligible. • [redacted] • [redacted]

Requested Action(s)	Please complete a Death Notification Record (DNR) for each incorrectly reported donor and provide a corrective action plan detailing how the OPO will ensure compliance in reporting an eligible death as defined in OPTN Policy 1.2.
Explanation	The Manager, Organ Services had recently assumed the responsibility of classifying referrals as an "eligible death" and mistakenly classified these two referrals incorrectly. Additionally, there was not a system to check the accuracy of the classification; the accuracy of information reported was dependent upon one person making the determination by themselves. Root Cause: Lack of training and lack of a QA process.
Corrective Action Plan and Estimated Completion Dates	1. The OPO donor records for [redacted] 1141 and [redacted] have been updated to reflect that they were both eligible donors. Death Notification Records were created in UNET for [redacted] and [redacted] on September 14, 2016. 2. The Manager, Organ Services or designee will be required to determine referral classification no less than once per week and a designated Quality team member will be required to review the referral classifications of the Manager, Organ Services or designee no less than once per week. These individuals will be required to discuss referral classification in the event of a disagreement. These changes will be implemented no later than October 5, 2016. 3. The Manager, Organ Services or designee will indicate the referral classification in the electronic medical record system. A designated Quality team member will write "Verified" upon verification and agreement with Manager, Organ Services' referral classification in the appropriate comments section in the electronic medical record system, which will signify review of the eligibility criteria. These changes will be implemented no later than October 5, 2016. 4. Policy ORG C6.000 Data Submission will be updated to reflect that the Manager, Organ Services or designee and a member of the Quality team will make the determination of "eligible death" together prior to that information being entered into UNET. The policy update will become effective no later than October 5, 2016. 5. The Manager, Organ Services and the Quality staff will be trained on these changes prior to implementation and no later than October 5, 2016. Effectiveness assessment:

	By the tenth of the month, the preceding month's brain deaths and eligibility classifications will be audited by the COO or CEO or designee to ensure compliance with the process.